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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,668	09/30/2005	Kazuo Imose	TEI-0135	5514

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EXAMINER	
JANG, CHRISTIAN YONGKYUN	
ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,668	IMOSE, KAZUO	
	Examiner	Art Unit	
	CHRISTIAN Y. JANG	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on July 27th, 2009. Claims 1-15 are pending in the instant application. Claims 14 and 15 have been newly added. Amendments to claims 1, 4, 6, 10, 11, and 13 are acknowledged by the examiner.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavie et al. (US 2003-0004423) in view of Brown (US 2001/0011224).

4. As to claim 1, Lavie teaches an examination apparatus comprising a non-implantable biological information monitoring system, which has a unit for measuring and recording an airflow information (207), a unit for measuring and recording an EKG wave form of the subject patient having an electrode part which can be stuck on the skin of the subject patient ([0066]), wherein the monitoring system is constituted such that the subject can move with the monitoring system attached on the body (no restraint or any other means are taught by Lavie to restrict movement), an analysis unit for analyzing the enhanced state of sympathetic nerves based on the measured EKG wave form ([0077], [0113]), an output part for displaying or printing both of a transition of respiratory workflow and a transition of the enhanced state of sympathetic nervous of

the subject patient (Fig. 13, 550). While Lavie does not teach the use of the apparatus in selecting patients for whom an oxygen therapy is effective among patients having chronic heart failure, it teaches a device for detection of congestive heart failure, and is capable of performing the intended use language ([0060]). Lavie fails to teach an editor part for selecting a zone to be subjected to data processing among biological information through visual identification. However, Brown teaches a user input system including a display menu item for the selection of a specific period of time ([0064]). In addition, it would be obvious to enable this feature to allow a caretaker to obtain analysis over a time period the caretaker deems to be relevant to the diagnosis and treatment of the subject. As such, it would have been obvious to one of ordinary skill in the art to modify the examination apparatus of Lavie with an editor for selecting a zone to be subjected to data processing as taught by Brown to allow the user to manually select a relevant time period for data analysis.

5. As to claim 2, Lavie teaches the use of heart rate variability for analyzing the state of the sympathetic nerves ([0090-0091]).

6. As to claim 3, Lavie teaches the analysis unit for analyzing synchronization of transition of the respiratory state in a Cheyne-Stokes respiratory symptom in which apnea and respiratory states are repeated with transition of abnormal enhancement of sympathetic nerve ([0019], claim 14).

7. Claims 4, 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavie et al. (US 2003-0004423), Brown (US 2001/0011224), and further in view of

Krachman et al. ("Comparison of Oxygen Therapy with Nasal Continuous Positive Airway Pressure on Cheyne-Stokes Respiration During Sleep in Congestive Heart Failure").

8. As to claims 4 and 6-9, the combined teachings of Lavie and Brown disclose the invention substantially as claimed. Lavie and Brown fail to teach a supplying apparatus of an oxygen-enriched gas for respiration for the purpose of carrying out the oxygen therapy. Krachman teaches the effectiveness of using oxygen therapy in patients with CHF. As such, it would have been obvious to one of ordinary skill in the art to modify the examination apparatus of Lavie incorporating an editor for selecting a zone to be subjected to data processing as taught by Brown with an oxygen therapy device taught by Krachman to supply treatment for the symptoms monitored by the examination apparatus.

9. As to claims 10-13, the combined teachings of Lavie, Brown, and Krachman disclose the invention disclose the invention substantially as claimed. The combined teachings of Lavie, Brown, and Krachman do not teach selecting a patient who exhibits the results that an arterial oxygen saturation is not higher than a predetermined threshold value. However, Lavie disclosure includes means to determine blood oxygen saturation ([0065]).. Oxygen toxicity, severe hyperoxia caused by breathing oxygen at elevated partial pressures, is a well known and established medical concept. Thus, it is the examiner's position that it would have been obvious for one of ordinary skill in the art to modify the examination apparatus of Lavie incorporating an editor for selecting a zone to be subjected to data processing as taught by Brown and an oxygen therapy

device taught by Krachman to exclude patients who exhibit oxygen levels above an established saturation point so that the therapy they receive do not result in hyperoxia.

10. Claims 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lavie et al. (US 2003-0004423), Brown (US 2001/0011224), Krachman et al., and further in view of Thomas et al. (US 2004/0144383).

11. As to claim 5, the combined teachings of Lavie, Brown, and Krachman fail to teach the supplying apparatus allows the gas to be regulatable to a predetermined range. However, Thomas teaches a therapeutic system wherein the supplying apparatus of an oxygen-enriched gas for respiration is constituted to allow flow rate of the oxygen-enriched gas for respiration to be regulatable within a predetermined range so that the flow rate becomes the amount prescribed on the basis of the result displayed or printed by the output part of the examination apparatus ([0014], lines 1-11). As such, it would have been obvious to one of ordinary skill at the time of the invention to modify the examination apparatus of Lavie incorporating an editor for selecting a zone to be subjected to data processing as taught by Brown and an oxygen therapy device taught by Krachman with the airflow regulation taught by Thomas so that the amount of oxygen delivered to the user is regulated to be in therapeutic range.

12. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavie et al. (US 2003-0004423), Brown (US 2001/0011224), and further in view of IBM DiskOnKey ("8MB USB Memory Key – Overview").

13. As to claims 14 and 15, the combined teachings of Lavie and Brown disclose the invention substantially as claimed. Lavie fails to teach a recording medium detachably attachable to the monitoring system. However, a portable and detachably attachable recording medium has been on sale by IBM since the year 2000. Detachable recording medium would enable the user to easily port the measurement data for further analysis or transfer without the need to transfer the device itself. As such, it would have been obvious to one of ordinary skill in the art to modify the examination apparatus of Lavie incorporating an editor for selecting a zone to be subjected to data processing as taught by Brown to utilize a detachable recording system such as the one sold by IBM to allow for ease of data portability.

Response to Arguments

14. Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon. - Fri. (8AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

CJ
/C. Y. J./
Examiner, Art Unit 3735
12/17/09